Case IPR2018-00943
Patent No. 7,919,499
Declaration of Sara K. Quinney, Pharm.D., Ph.D.
Attorney Docket No. AMNEAL 7.1R-005

UNITED STATES PATENT AND TRADEMARK OFFICE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD
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AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

ALKERMES PHARMA IRELAND LIMITED,

Patent Owner.

Patent No. 7,919,499 to Elliot Ehrich
Issue Date: May 19, 2015
Title: NALTREXONE LONG ACTING
FORMULATIONS AND METHODS OF USE

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Inter Partes Review No. IPR2018-00943

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(Exhibit 1062)

**DECLARATION OF SARA K. QUINNEY, Pharm.D., Ph.D. IN SUPPORT
OF PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

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I, SARA K. QUINNEY, declare and state as follows:

I.   INTRODUCTION

1.   I am a U.S. Citizen and a resident of the State of Indiana.

2.   I have been retained by Lerner, David, Littenberg, Krumholz & Mentlik, LLP ("counsel") to provide my opinions in the field of clinical pharmacology and pharmacokinetics for purposes of this *Inter Partes* Review ("IPR"). I have read and understand U.S. Patent No. 7,919,499 ("the '499 Patent") (Ex. 1001) as well as all other references discussed in this declaration. I am being compensated for my time in an amount consistent with my customary consulting fee, and my compensation is not contingent on my opinion or the outcome of this proceeding.

II.   BACKGROUND AND QUALIFICATIONS

3.   I am an expert in pharmacokinetics, which is frequently abbreviated as "PK." Pharmacokinetics is the branch of pharmacology that describes and quantifies the movement of a drug within the body of a living organism. Pharmacokinetics provides information on mechanisms of drug absorption, distribution, metabolism, excretion, and transport (ADMET). My background and qualifications are set forth in my *curriculum vitae*. (Ex. 1063.) It contains a description of my education, academic appointments, professional activities, research grants, presentations, service as a reviewer for professional journals,

published articles in peer reviewed scholarly journals, teaching responsibilities, and thesis supervision.

4.   I hold a primary appointment as an Assistant Professor of Obstetrics and Gynecology at Indiana University School of Medicine (IUSM). Additionally, I hold adjunct appointments in the Division of Clinical Pharmacology, Department of Medicine in IUSM, the School of Informatics and Computing at Indiana University Purdue University Indianapolis (IUPUI), and the Department of Pharmacy Practice, College of Pharmacy, Purdue University.

5.   I am the Associate Director of the Indiana Clinical and Translational Sciences Institute (CTSI) Disease and Therapeutic Response Modeling Program. This program provides training in pharmacometrics and quantitative systems pharmacology, including pharmacokinetic/pharmacodynamic (PK/PD) modeling, physiologically based pharmacokinetic (PBPK) modeling, and machine learning. I am also a member of the Center for Computational Biology and Bioinformatics (CCBB) at the Indiana University School of Medicine.

6.   I obtained my Doctorate in Pharmacy from Purdue University in 2000 and obtained my Ph.D. in Pharmacy Practice from Purdue University in 2004. I subsequently completed a Postdoctoral Fellowship in Clinical Pharmacology at the Indiana University Division of Clinical Pharmacology in 2007 and completed a Postdoctoral Fellowship in Bioinformatics and Biostatistics at the Indiana

University Department of Biostatistics in 2009. I joined the Indiana University School of Medicine as an Assistant Research Professor in 2009, and since 2013, I have been an Assistant Professor in the Division of Clinical Pharmacology and in the Department of Obstetrics and Gynecology at the Indiana University School of Medicine. Since 2013, I have also been a member of the Center for Computational Biology and Bioinformatics and since 2015, I have been an Associate Director of the Indiana CTSI Disease and Therapeutic Modeling Program within the Indiana University School of Medicine.

7.   Since 2009, I have designed and directed a number of clinical PK studies, primarily in pregnant women. For instance, I conducted a PK study to evaluate the effect of pregnancy on the PK of nifedipine administered to women with preterm labor. In collaboration with other investigators at IUSM, I have evaluated the impact of pharmacogenomic variants in CYP3A enzymes on the PK and PD of betamethasone for fetal lung maturation. I am currently conducting a study in women in their third trimester of pregnancy to evaluate the effect of hepatitis C virus (HCV) on the clearance of buprenorphine. Therefore, I am well versed in the design and conduct of clinical pharmacology studies, especially studies of PK, PD, and pharmacogenomics.

8.   My research also encompasses the area of opiate use disorder. I have conducted a clinical study evaluating the relationship between exposure of R- and

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